

2009 HISPC Seminar Series

Health Information Security and Privacy Collaboration (HISPC) Phase III—Multi-State Collaboration

Interorganizational Agreements (IOA)

June 30, 2009

Presenters:

Roy Wyman, Jr., North Carolina

William O'Byrne, New Jersey

Kevin DeWald, South Dakota

Carolyn Heyman-Layne, Alaska

Mark Gordon, New Jersey

Jo Ellen Whitney, Iowa

Moderator: Stephanie Rizk (RTI)

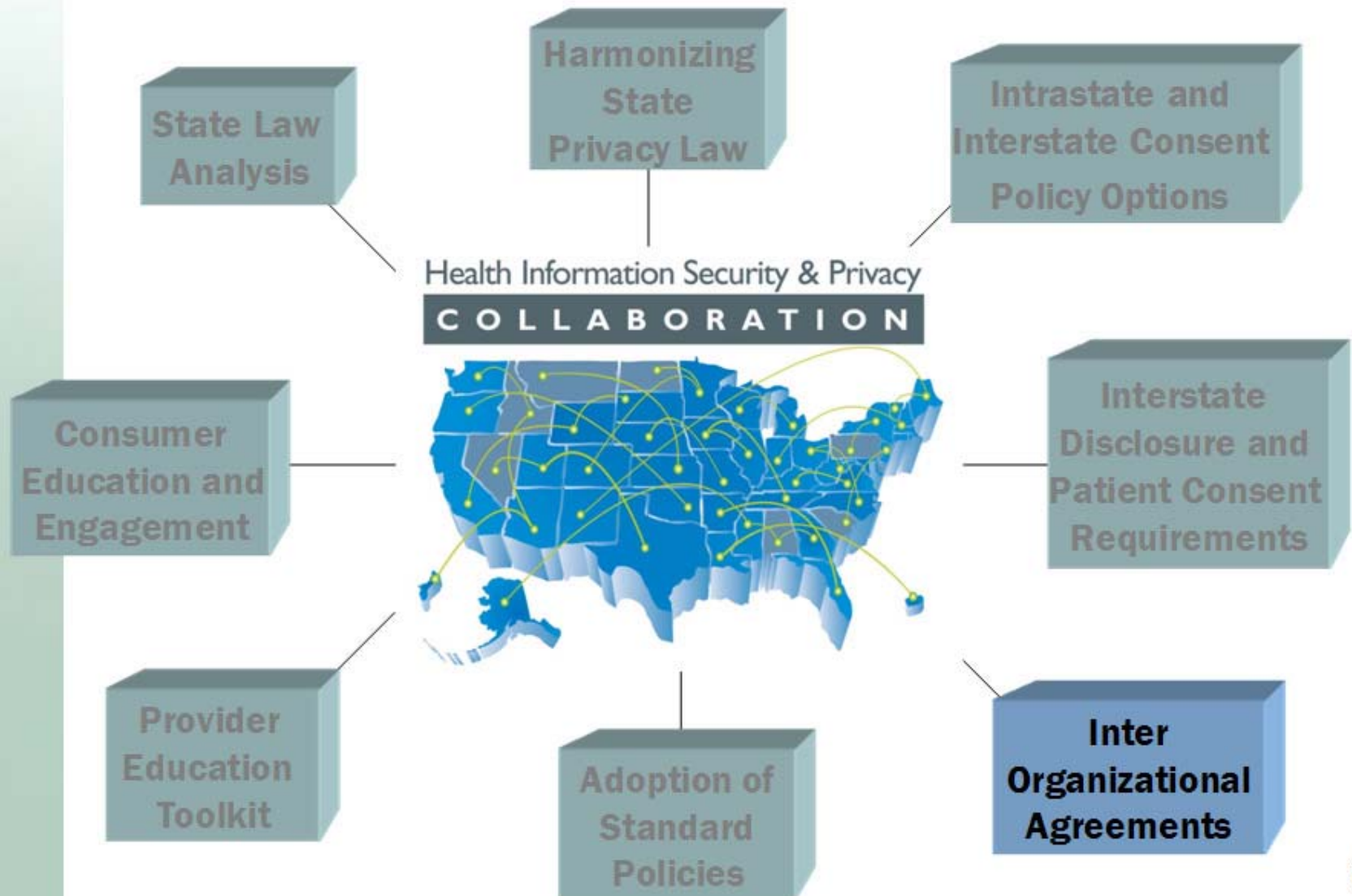


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<http://healthit.hhs.gov/HISPC>

HISPC Phase III

HEALTH INFORMATION SECURITY & PRIVACY
COLLABORATION



IOA Introduction And National Relevance

Roy H. Wyman, Jr.

Attorney, Williams Mullen Law Offices
North Carolina

Why Do We Do This?

- Time
- Complexity
- Liability

- **Products**
 - Private-to-Private Data Sharing Agreement
 - User Guide
 - Public-to-Public Data Sharing Agreement
 - User Guide
 - Master Document of Grouped Contract Provisions
 - Final Report
 - DURSA Crosswalk

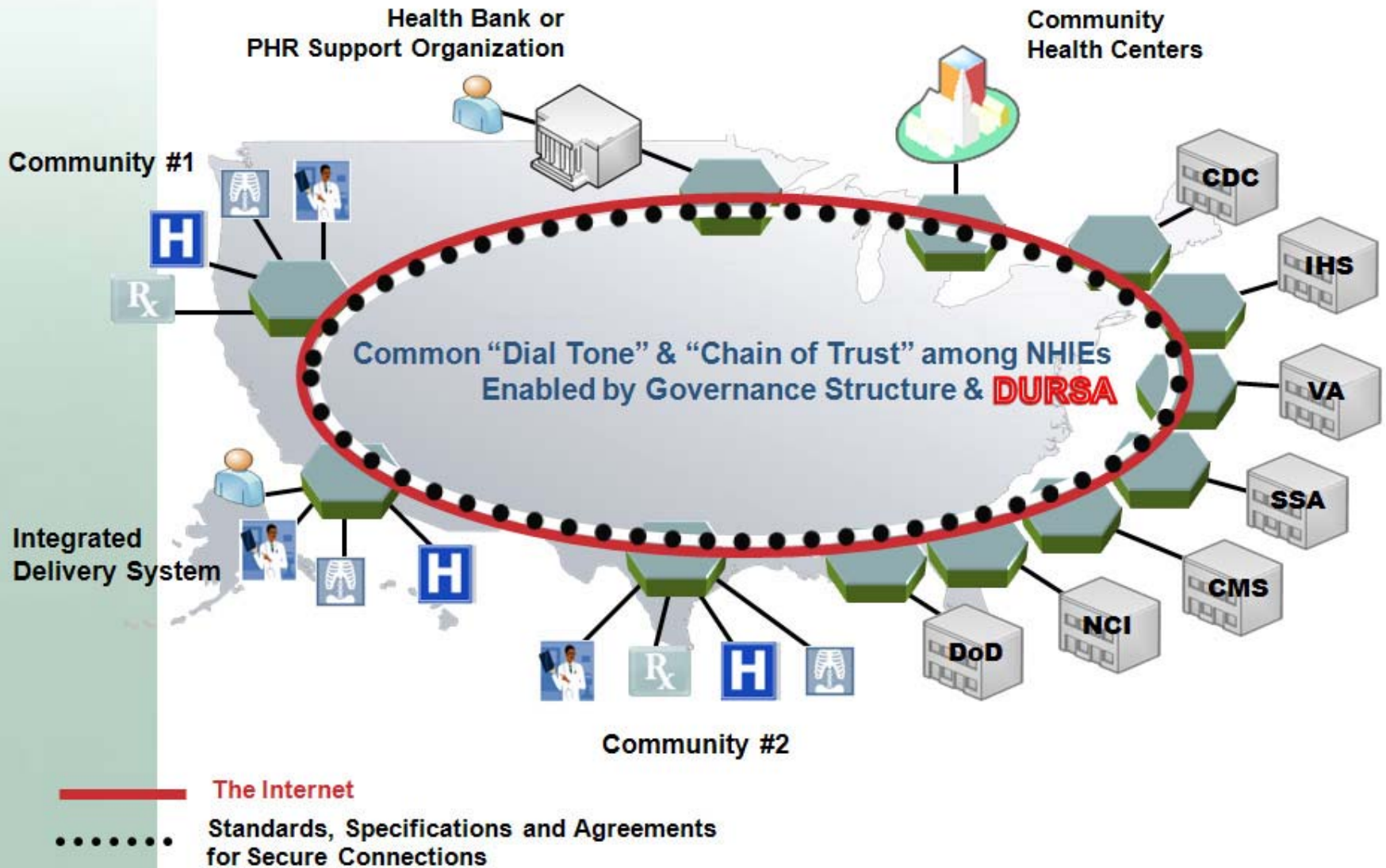
National Relevance

- **National Relevance—Public to Public**
 - Immunization connecting:
 - Iowa
 - South Dakota
 - New Jersey
 - New York
 - Philadelphia
 - Guam
 - Agreement endorsed by AIRA
 - CDC, Region IV pilot
 - North Carolina/South Carolina exchange of epidemiological information

National Relevance

- **National Relevance—Private to Private**
 - Universal agreement for all providers
 - Assumes point-to-point, but can be used for networks
 - Can be used cross-state or intrastate
 - Reviewed and approved by North Carolina NHIN participant

NHIN

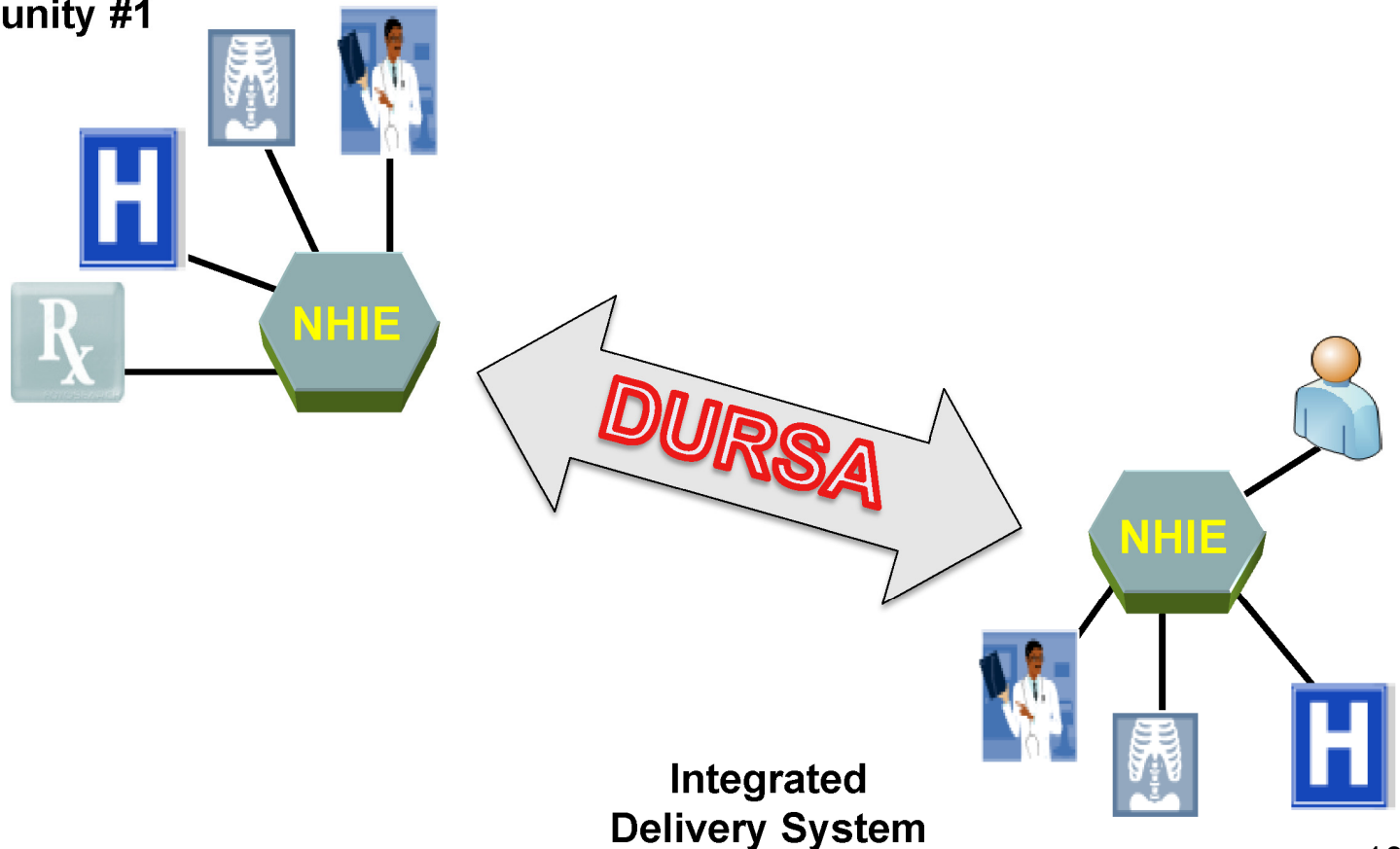


NHIN

“Network of Networks”

DURSA Enables Exchange among NHIEs via the NHIN

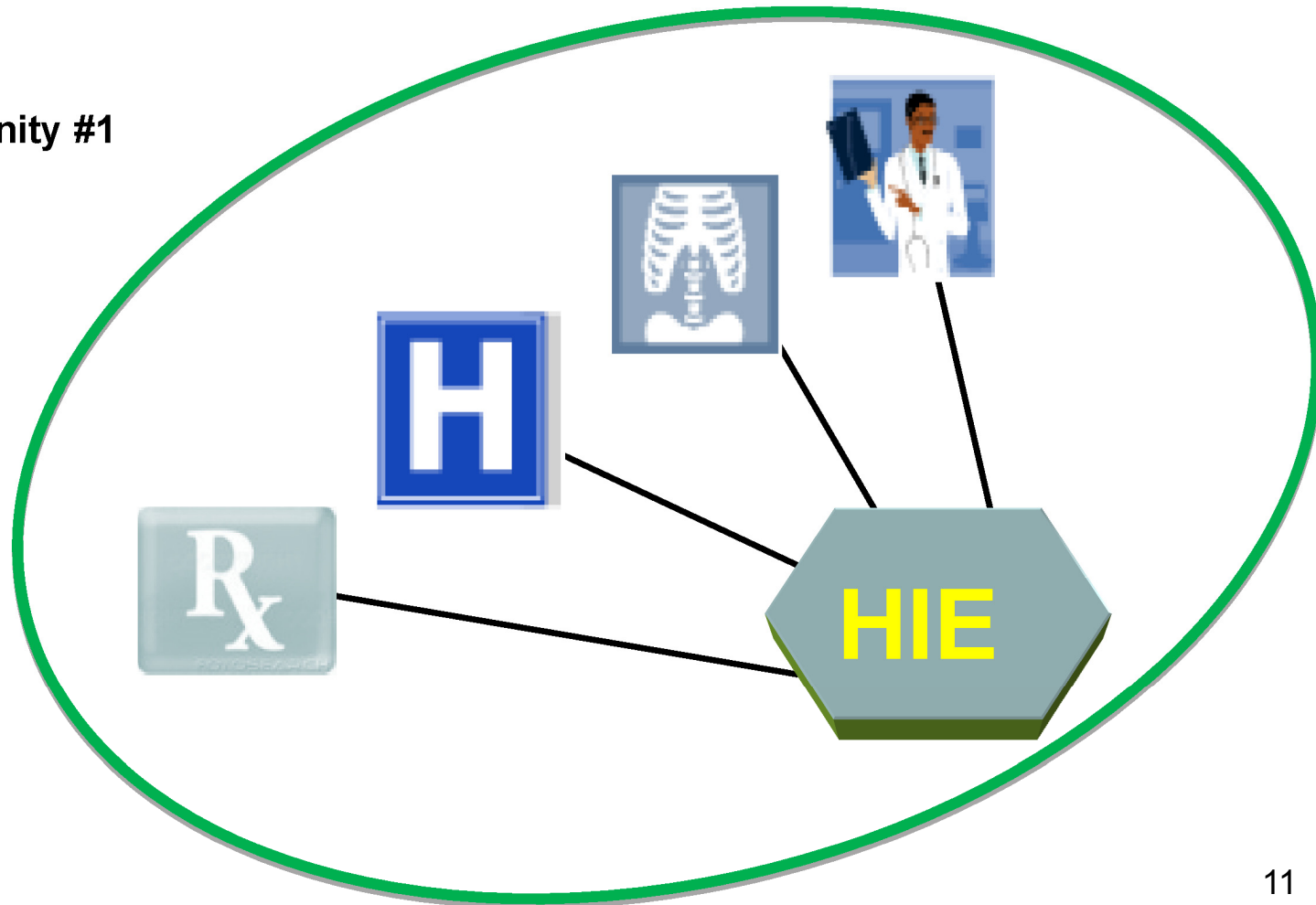
Community #1



“Network of Networks”

HIEs within the NHIN Have Separate Agreements

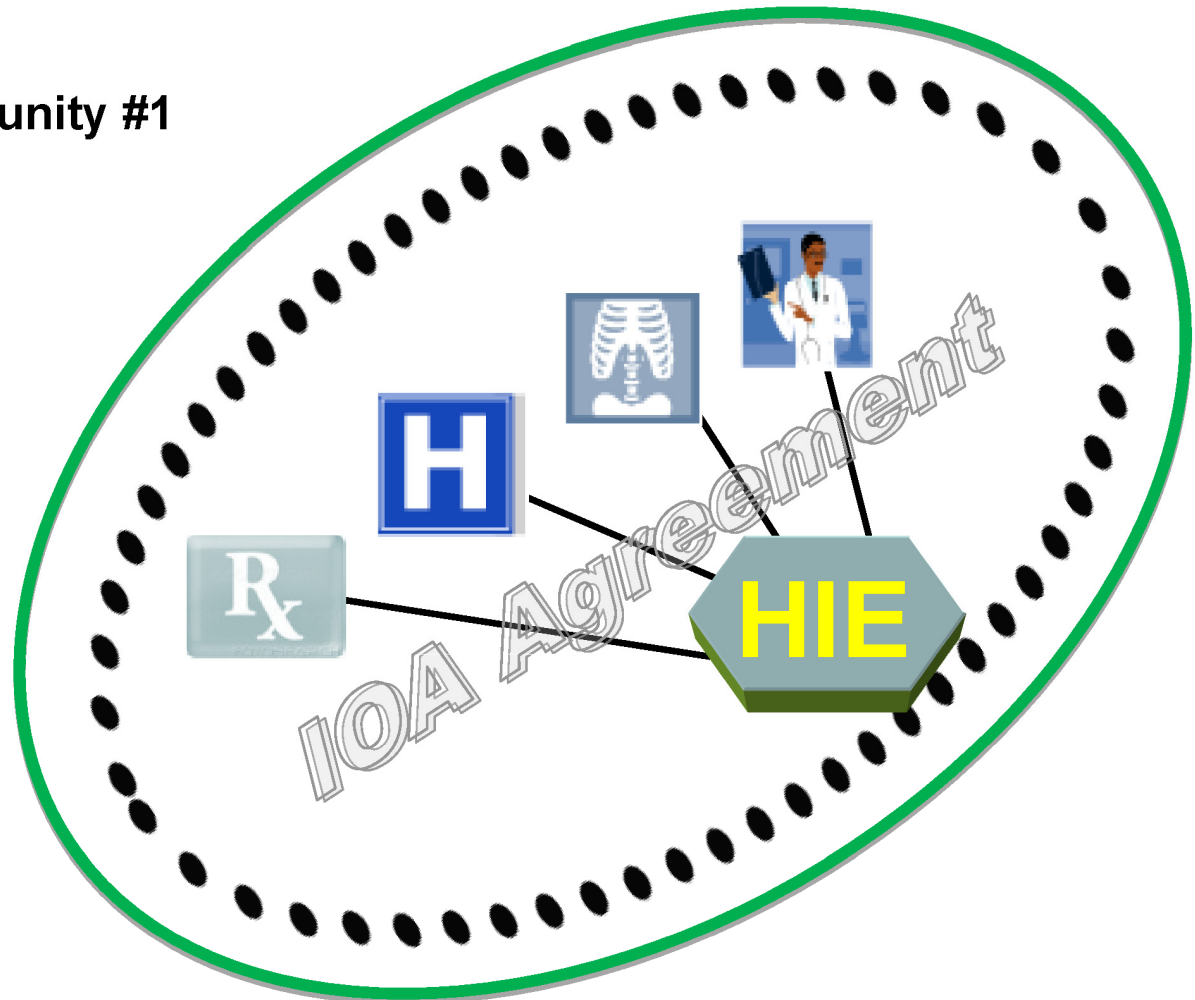
Community #1



“Network of Networks”

A Community May Create a Community HIE “Utility”

Community #1



The IOA Collaborative Now: Phase III Extension

- **Phase III Extension:**
 - Private-to-public data sharing agreement
 - Pilots in North Carolina and Guam
 - Immunization registry analysis
 - New Jersey-Philadelphia exchange
 - Iowa-Alaska private-to-private pilot

IOA Legal Process and External Agency Review

William O'Byrne, J.D.

State Coordinator, Office for e-HIT Development
New Jersey

IOA Collaborative Legal Work

- Documents Library
 - Began with 48 agreements and documents
- Classification Scheme
 - Guide to read the library documents and categorize the provisions
 - Classification categories include document source, document type, and document subject matter
- 350+ Page Master Document of Contract Provisions
 - Compilation of document library into one document using the classification scheme categories

IOA Collaborative Legal Work

- 2 Model Data Sharing Agreements
 - Public Health Data Sharing Agreement: to share public health data electronically between two or more public health entities
 - Private to Private Data Sharing Agreement: to share data electronically between two or more private entities
- Core Privacy and Security Provisions
 - A resource of language for other agreements or to insert into existing agreements
- Two User Guides
 - One for each agreement outlining how the DSAs were developed, also includes other resources
- DURSA Crosswalk
 - Comparison document of the NHIN/DURSA workgroup document provisions to the IOA model DSAs' provisions

IOA Collaborative Legal Work

Documents Library

- Sources
 - Individuals
 - CMS/other agencies
 - States
 - Private entities
 - Markle Foundation
- Divided up between the seven collaborative member states/territories for review

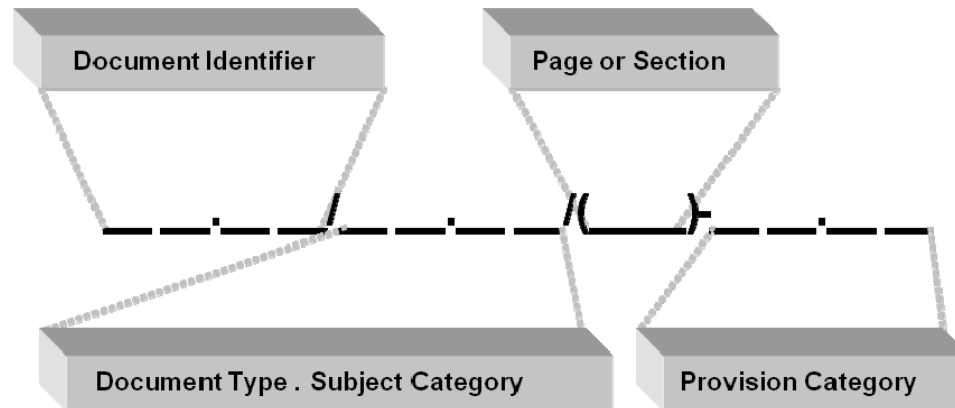
IOA Collaborative Legal Work

Classification Scheme

- Classification Headings
 - **Document source**
 - **Document type**
 - **Document subject matter**
 - Definitions
 - Recitals
 - Statement of relationship
 - Data recipient requirements
 - Data provider requirements
 - Software/hardware
 - Privacy
 - Security
 - Term and termination
 - Fees or consideration
 - Confidentiality of proprietary info
 - Disclaimers
 - Insurance
 - Indemnification
 - Boilerplate, such as
 - Applicable law
 - Notice
 - Waiver

IOA Collaborative Legal Work

Classification Scheme



- The following is an example of this classification scheme in application:

MF.01/hh.06/(s2)-DE.01

- Translation: Markle Foundation, A Model Contract for Health Information Exchange, an eHIE-to-eHIE document covering general data sharing, Section Two—Definition of Authorized User.

IOA Collaborative Legal Work

350+ Page Master Document of Grouped Contract Provisions

- Reviewed by state legal work groups
- Identify provisions that conflicted with state laws and regulations
- Rank preferred provision language
- Compilation of state results and language preferences into tables built on classification categories
- Parking lot issues—work for 2009

IOA Collaborative Legal Work

Continued Review

- Comparison of chosen provisions with Markle Foundation provision categories
- Final selection of provisions, focused on simple language
- Drafting new provisions when necessary
- Refining the agreements

IOA Collaborative Legal Work

IOA Model Agreements

- Public Health Data Sharing Agreement
 - Electronic sharing
 - Several public health entities
 - Two or more immunization registries
- Private Entity Data Sharing Agreement
 - Electronic sharing
 - Several private entities
 - Two or more hospitals

IOA Collaborative Legal Work

- IOA DSAs: Core language only
- User must add details in attachments
 - Additional uses of data
 - Licenses to access data
 - Technology standards for security
 - Timelines expectations for data delivery
 - Mitigation of breaches
 - Policies and procedures for privacy and security
- IOA future work: Draft attachment language

IOA Collaborative Legal Work

Privacy and Security Core Provisions

- Definitions
- Purpose and scope
- Participant requirements
- Use and access to protected health information
- Agreement to comply with laws and regulations
- Insurance
- Subrogation
- Governing law/choice of law

IOA Collaborative Legal Work

Policy Decisions and Guiding Principles

- Drafted for use across all jurisdictions
- HIPAA compliance was a guiding principle
- Each party will operate under and comply with its own applicable state law
- Each party's applicable state law will govern
- In the event that a dispute cannot be resolved, the parties will look to federal law and the growing body of federal common law
- Participation voluntary and can be terminated at will
- More in User Guides

IOA Collaborative Legal Work

User Guides

- The guides are for parties entering into electronic health information exchanges
- Guide contents
 - Background
 - Mission
 - Steps taken
 - Policy decisions and guiding principles
 - Completing the agreement
 - Additional considerations
 - Additional resources

IOA Collaborative Legal Work

Crosswalk to DURSA

- Comparison of the IOA DSAs' provisions to the NHIN/DURSA document, specifically to
 - Permitted future uses
 - Governing body
 - Security
 - Governing law
 - Subrogation
 - Accuracy of data
 - Liability
 - Dispute resolution

IOA Collaborative Legal Work

Parking Lot Issues for 2009

Public to private data sharing agreement—IOA extension period task

- Alternative dispute resolution
- Minimum standards for privacy/security
- Sensitive information
- Promoting the further sharing of information—IOA extension period task, NJ–Philadelphia immunization data exchange
- Audit and audit trails

External Review and Feedback

- CDC Region IV
 - Considering use of the IOA Public Health DSA or its core provisions
- American Immunization Registry Association (AIRA)
 - Endorsed the IOA Public Health DSA for use in all states for the electronic sharing of immunization data
- New Jersey–Pennsylvania
 - New Jersey and Philadelphia now, and Pennsylvania in the future, are using the IOA Public Health DSA to share immunization data electronically

External Review and Feedback

- New Jersey–New York City–New York State
 - Had a demonstration project to share immunization data at the end of 2007; will use the AIRA document to expand into a regular electronic sharing of immunization data
- Kansas
 - Reviewed the IOA Public Health DSA; will use some of the provisions in their documents possibly as early as this year
- Public Health Data Standards Consortium (PHDSC)
 - Endorsed the Public Health DSA for national use
- The Future
 - Creation of a metropolitan immunization data sharing for NJ, NY, PA, DE, FL, and PR.
 - Use the IOA Public Health DSA for other public health registries

IN WITNESS WHEREOF, the Participants have caused this Agreement to be signed by their duly authorized representatives as of the Effective Date.

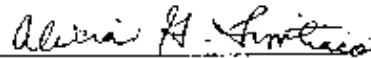
Signatures:



Michael W. Lynch, M.D.,
Acting Governor of Guam

NOV 28 2008

Date



Alicia G. Limtiaco, Attorney General
Office of the Attorney General

11/25/08

Date



Peter Roberto, Acting Director
Department of Public Health and Social Services

11/19/08

Date



Mary Jones, Deputy Director
Iowa Department of Public Health

10-31-08

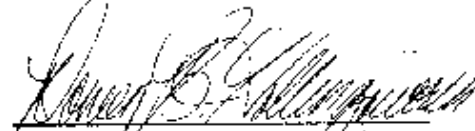
Date

Susan M. Walsh, MD, FACP
Deputy Commissioner

Placeholder for New Jersey
New Jersey Department of Health and Senior Services

2/26/09

Date



Doneen Hollingsworth, Secretary of Health
South Dakota Department of Health

11-7-08

Date

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IOA Pilots and Evaluation

Kevin DeWald

Senior Director, Department of Health,
South Dakota

and

Carolyn Heyman-Layne

Attorney, Dorsey & Whitney
Alaska

Public Health Pilot



Guam, Iowa, New Jersey, and South Dakota

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Demonstrates

- Parties will sign a cross-state/territory data sharing agreement developed by a national privacy and security project workgroup and
- Feasibility of cross-state/territory data exchange, in light of the distinctiveness of the registry systems.

Technical Details

2-Way Exchange

Iowa, South Dakota:

- Ages: 0–25
- Iowa Counties : Lyon, Plymouth, Sioux, Woodbury
- South Dakota: Lincoln, Minnehaha, Union
- 151,000 patient records
- 2.03 million vaccine records

4-Way Exchange

Guam, Iowa, New Jersey, South Dakota:

- Age 18 (Born in 1990)
- 50,000 patient records
- 662,000 vaccine records

Private Entity Pilot

- North Carolina
 - Duke University
 - Western North Carolina Health Network
 - Blue Cross/Blue Shield of North Carolina
 - North Carolina Medical Society
 - North Carolina DHHS
 - First Health Hospital
 - And others
- Alaska
 - Alaska eHealth Network

Private Entity Pilot

- Private entities and legal counsel outside the IOA
- Negotiations among numerous participants on IOA model agreement
- Minor revisions suggested
- Alternative language discussed and selected
- Parties asked to approve final version to be executed at a later time

Results: Private Pilot

- 17 total organizations participated
- Included legal, non-legal, IT, and administrative
- Original agreement revised slightly to address newly raised issues
- Increased awareness of IOA work
- Increased likelihood of future use
- Limits length of future negotiation and drafting
- New topics identified for future agreements

Results: Private Pilot

“We wish that we had this document three years ago so that we could have saved a great deal of time and effort.”

– Private pilot participant from a large provider network

Phase III Extension

- Iowa and Alaska physician-to-physician exchange
- Continuity of care record exchange
- Real-life testing of private-to-private document and implementation process

How to Use the IOA Documents Work Product for Your Organization

Mark S. Gordon

Senior Fellow/Director of Healthcare Information
Networks & Technologies (HINT)
Thomas Edison State College, New Jersey

How To: Public and Private eHIE

- Gather participants/additional interested entities
- Include/inform senior management, legal and technical representatives throughout project
- Determine scope and objectives of public or private eHIE
- Obtain support of senior management/Commissioner/Board
- Set scheduled meetings/encourage transparency
- Establish management team/liaisons and assign responsibilities—build trust

How To: Public and Private eHIE

- Review IOA Report/DSA User Guides and consider policy decisions and guiding principles
- Use IOA Documents as appropriate (i.e., DSA endorsed by AIRA and PHDSC) to save time and money
- Review additional considerations—legal, administrative, financial, and technical; resolve barriers
- Obtain approvals for project implementation from senior management and sign agreements

How To: Public and Private eHIE

- Pilot test, train staff, and initiate exchange
- Audit, feedback/improve, enhance/expand eHIE
- Publicize eHIE's public/population health improvements for data access/accuracy, quality of care, and patient safety

How To: Private eHIE

- Use IOA documents as appropriate to save time and money; revise DSA if necessary
- Determine common goals, objectives, and outcomes
- Resolve issues such as governance, ownership, and liability; due diligence; review policy and procedures
- Individual/organization change; re-engineer
- Educate and train staff, pilot test, and initiate exchange
- Publicize data privacy/security safeguards for eHIE improved quality of care and patient safety

Closing and Future Vision

Jo Ellen Whitney

Attorney, Davis Brown Law Firm
Iowa

HISPC and the IOA Collaborative

Promoting interoperable electronic health information exchange through Model Data Sharing Agreements

Public Health

HEALTH INFORMATION EXCHANGE AGREEMENT
between

Guam Department of Public Health and Social Services (DPHSS),
Iowa Department of Public Health (IDPH),
New Jersey Department of Health and Senior Services (NJDHSS) and
South Dakota Department of Health (SDOH)

for

Pilot Test of the Guam-Iowa-New Jersey-South Dakota Immunization Data Exchange Project

Participants are:
The Health Information Security and Privacy Collaborative (HISPC)
Interoperational Agreements (IOA) Collaborative - Public Health Workgroup
October 2008

Introduction

Background

This agreement is designed to facilitate secure, electronic exchange of Immunization Records between Guam, Iowa, New Jersey and South Dakota, using each state's computerized registry.

States and territories across the U.S. have developed electronic immunization registries to capture immunization records for their residents. The registries are a vital public health tool for monitoring immunization rates and status, and enable healthcare providers to access a database of immunization histories for their respective patients.

Immunization registries have been partially funded through the Centers for Disease Control and Prevention (CDC), yet states have given autonomy in choosing the design and technical specifications for their respective systems. Such is the case for Guam, Iowa, New Jersey and South Dakota; each maintains a distinct immunization registry system.

The Pilot Test of the Guam-Iowa-New Jersey-South Dakota Immunization Data Sharing Project is designed to demonstrate:

- that parties will sign a cross-state data sharing agreement developed by a national Privacy and Security project workgroup; and
- the feasibility of cross-state data exchange, in light of the distinctiveness of the registry systems. Evaluation of several components (e.g., technology, privacy/security, legal processes,

Page 1 of 10/10/2008

*The Health Information Security and Privacy Collaborative (HISPC) Interoperational Agreements (IOA) Collaborative is a copyright of 7 state and territorial entities: AK, CA, HI, IL, IN, PA, SD) housed at the Office of the Federal Coordinator for Health Information Technology, during HISPC's multi-part data sharing pilot.

Private Entities

Health Information Exchange Agreement
Private to Private Pilot

This Health Information Exchange Agreement ("Agreement") is made effective this ____ day of ____, 20__ the "Effective Date", by and between:

____, a _____ (type of entity) organized under the laws of the State (or Territory) of _____, and having its principal place of business at _____, and _____, a _____ (type of entity) organized under the laws of the State (or Territory) of _____, and having its principal place of business at _____, ("Participant" and together, "Participants").

WITNESSETH:

WHEREAS, Participants have established secure, electronic patient data exchange systems to allow Authorized Users (as defined below) to electronically exchange patient information; and

WHEREAS, Participants have entered into agreements with health care entities under which such entities have agreed to provide Participants with access to resident patient information generated by participating entities; and

WHEREAS, Participants desire to obtain information located on each other's Systems (as defined below) to allow Authorized Users to access patient information for the continuing care and treatment of patients and beneficiaries; payment of claims and healthcare operations; and

WHEREAS, each Participant desires to further the privacy and security of Protected Information (as defined below) and its System;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants and agreements set forth below, and other good and valuable consideration, the receipt and legal sufficiency of which are hereby acknowledged, and wishing to be legally bound hereby, the Participants have agreed as follows:

- Definitions.**
 - "Agreement" has the meaning set forth in the Preamble.
 - "Authorized User" shall mean a Participant's employee, agent, assign, representative, independent contractor, or other person or entity authorized by such Participant to access, use or disclose information from another Participant's System.

* This document should be reviewed when a Participant's description of the Agreement is not well-defined, such as a HIPAA, or other state or federal privacy law.

Closing: Key Achievements

- Documents Library
- Classification Scheme
- Public Health Data Sharing Agreement
- Private Entity Data Sharing Agreement
- Core Privacy and Security Provisions
- DURSA Crosswalk
- Public Health Pilot
- Private Entity Pilot
- User Guides for Implementation
- Final Report

Closing: Key Achievements

American Immunization Registry Association (AIRA)

December 2008

“...formally endorsed by AIRA for use by all states and public health agencies for the interoperable exchange of public health immunization data.”

Closing: Key Achievements

Public Health Data Standards Consortium (PHDSC)

February 2009

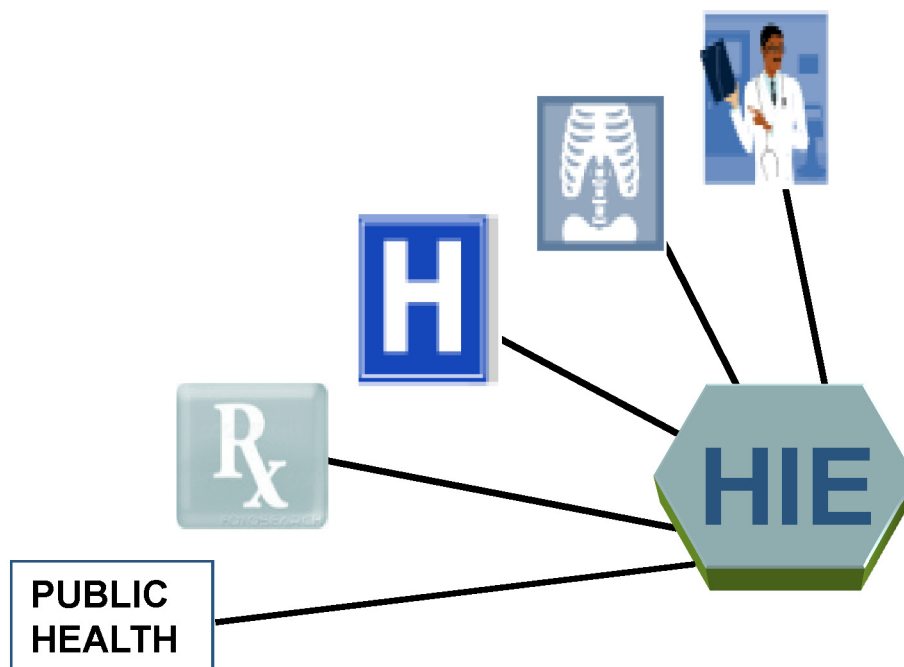
“...the availability of this model agreement will greatly simplify the establishment of much-needed health information exchanges between public agencies across state lines...”

IOA Model Agreements become standard legal agreements for point-to-point electronic health information exchange between public health agencies and between private entities

What's Next?

Future Vision

Develop standardized agreements for community HIEs to support the NHIN?



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**Office of the National Coordinator (ONC) for
Health Information Technology**



Department of Health & Human Services
Office of the National Coordinator for
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turning knowledge into practice

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Questions?

Thank You for Attending

- Please visit <http://healthit.hhs.gov/HISPC> for full access to all of the products discussed today as well as information about the other HISPC collaborative products.